



## INSTRUCTIONS FOR RANDOMIZATION FORM (RAN)

### I. General Instructions

Complete this form to check for eligibility and to randomize a participant or cohabiting partner pair on the day of their study visit.

The RAN form asks if a participant is enrolling as part of a cohabiting partner pair. When a partner pair enrolls, the partner's RAN form must be completed on the day of their study visit.

See the Randomization Outline in section III for step-by-step instructions. **NOTE: COMPLETE ALL BASELINE DATA COLLECTION BEFORE RANDOMIZING A PARTICIPANT OR PARTNER PAIR. RANDOMIZING PRIOR TO BASELINE DATA COLLECTION COMPLETION IS A PROTOCOL VIOLATION.**

### II. Detailed instructions for each item

Enter form information for Participant ID selected from the study ID list:

0a. Enter the date the form was completed.

0b. Enter staff ID of the person who administered the form. The staff ID must be entered in the form to randomize. If left blank, an error message is returned.

#### A. Inclusion and Exclusion Criteria

1. Record if the participant is enrolling with a spouse or cohabiting partner pair.

- Select 1 (Yes) if participant is enrolling with a partner
- Select 0 (No) if participant is enrolling singly

1a. Record the partner participant ID. The participant ID and the partner ID must match for the pair to be randomized.

Enrolling with a partner is a special randomization case. Enter the data for each partner in parallel. Determine eligibility for the participants from within each participant's RAN form. The messages returned from the eligibility application provide instructions for data checking and/or the participant's eligibility for enrolling in ACHIEVE.

**Note:** Review the ACHIEVE Randomization Training Slides on the study website, particularly to review the eligibility criteria. Navigate to the Ancillary Studies->ACHIEVE->Training. (<https://www2.csc.unc.edu/aric/training-achieve>)

#### B. Eligibility Determination

Follow the directions on the screen for running the eligibility check application for the participant. The messages returned in the report give instructions for data checking and/or eligibility.

### C. Randomization

Follow the directions on the screen for randomizing. The report will return the result of the randomization including the treatment intervention group.

## III. ACHIEVE Randomization Outline

# ACHIEVE Randomization Outline

## General Notes

- If you encounter any problems during the randomization process, please contact the **CC (919-962-3079 or sheila\_burgard@unc.edu)**.
- Each participant of a cohabiting partner pair follows the same steps outlined below in parallel. Randomize partner pairs at the same time; both of the pair must be present.

## Prior to Randomization

- **PRESCREENING**
  - Enter the Telephone Screening Form (TSF)
  - Partially enter the Demographic Form (DEM) for de novo (name, DOB, education, contact information)
- **SCREENING**
  - Enter the Hearing Vision Screener (HVS). If HVS3=1 or 2, continue
  - Administer and enter the Mini-mental State Exam (MME6). RUN the eligibility application from the RAN form. If eligible for neurocognitive component, then continue.
  - Administer and enter the Audiology Assessment (AAF). RUN the eligibility application from the RAN form. If eligible for hearing component, schedule a BASELINE appointment.
- **BASELINE**
  - Re-run eligibility application from the RAN form to verify the participant (and partner if enrolling with a partner) are eligible. Proceed if participant (and partner) are eligible.
- Complete Informed Consent – be sure that the participant has signed the Informed Consent
- Complete Informed Consent Form (ICR)
- Complete the BASELINE exam

## Randomization

- **SINGLE PARTICIPANT**
  - Verify ICR form is complete, mark the form COMPLETE, then LOCK the ICR
  - Open and verify the RAN form is complete. Run the eligibility application.
  - Verify the displayed messages show the participant is eligible AND the RAN form is NOT LOCKED
  - SAVE and CLOSE the RAN form
  - Mark the RAN form as COMPLETE in the form grid
  - LOCK the RAN form
  - Click the magnifying glass in form grid to reopen the RAN form in BROWSE mode
  - Click the RANDOMIZATION link at the bottom to randomize the participant

- Report will return the treatment assignment

**OR**

- **COHABITING PARTNER PAIR** (referred to as PARTICIPANT and PARTNER)
  - Verify participant and partner ICR forms are complete, mark the forms COMPLETE, then LOCK both the participant ICR and partner ICR
  - Open one of the pair's RAN forms and run the eligibility application.
  - Verify the displayed messages show the participant and partner are eligible AND the RAN forms are NOT LOCKED
  - SAVE and CLOSE the RAN form
  - Open the form grid for the partner to verify the partner RAN form is complete
  - Mark the partner RAN form as COMPLETE in the form grid
  - LOCK the partner RAN form
  - Return to the participant RAN form
  - Mark the participant RAN form as COMPLETE in the form grid
  - LOCK the participant RAN form
  - Click the magnifying glass in form grid to reopen the participant RAN form in BROWSE mode
  - Click the RANDOMIZATION link at the bottom to randomize the participant and the partner
  - Report will return the treatment assignment